510 (k) Summary

FEB 1 2 2002

Summary of Safety and Effectiveness for Tuta's Arthroscopic Flushing Device.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Assigned 510(k) number K 020083

1. **Manufacturer's Name:** **Tuta Healthcare Pty. Limited**

   Manufacturer's Address: 318-332 Burnsbay Road
   Lane Cove , Sydney NSW 2066
   Australia

   Contact Person: Omid Souresrafil PhD

   Telephone Number: + 61 2 94270300 (Switchboard)
   + 61 2 9429 6381 (Direct)

   Fax Number: + 61 2 9427 5017

   Date: 24/12/01

2. **Device Name:**
   Trade Name: Arthroscopy Flushing Set
   Proprietary Name: Tuta Healthcare Arthroscopy Flushing Set 80.601
   Classification Name: Arthroscope Accessory (per 21CFR 888.1100)

3. **Legally Marketed Equivalent Device**

   Irrigation Set (K883300) – Edwards Orthopedic Division, Baxter Healthcare

   The. Arthroscopy Flushing set in the submission is substantially equivalent to Edwards Orthopaedic Division **(K883300),** Baxter Healthcare Irrigation - Set

   The Arthroscopy flushing set and the Edwards Orthopaedic Division devices are designed to provide irrigation, better visualization for the cleansing of surgical sights .

4. **Description of the intended use of the Device**

   The Tuta Healthcare Arthroscopy Flushing set is designed to provide controlled Irrigation to a joint during arthroscopic procedures. action of the hand pump help to remove blood, tissue debris, loose bodies and foreign matter from the joint cavity. The click clamps are used to block the flow of fluid.

   1. Distend the arthroscopy sight enabling good visibility and
   2. Flush the sight continuously to clear debris (loose bodies or cartilage fragments) away.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 2 2002

Omid Souresrafil, Ph.D.
Quality Assurance and Regulatory Affairs Manager
Tuta Healthcare Pty. Limited
318-332 Burns Bay Road
Lane Cove NSW 2066
Australia

Re: K020083
Trade/Device Name: Arthroscopy Flushing Set
Regulation Number: 881.1100
Regulation Name: Arthroscope and accessories
Regulatory Class: II
Product Code: HRX
Dated: January 8, 2002
Received: January 10, 2002

Dear Dr. Souresrafil:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. STATEMENT OF INDICTIONS FOR USE

510(k) Number (if known): K020083

Device Name: Arhtroscopy Flushing Set

Indications For Use:

The Tuta Healthcare Pty. Limited Arthroscopy Flushing set (80.601) is a gravity system Prescription Use (X), **(Per 21 CFR 801.109 for fluid management during arthroscopic procedures. During these procedures, the fluid is used to (1) distend the site, enabling good visibility and (2) flush it continuously to clear debris (loose bodies or cartilage fragments away).**

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020083

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (X)
(Per 21 CFR 801.109)